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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,817	04/08/2005	Thomas A Alheidt	P-5856	9959

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EXAMINER

SCHELL, LAURA C

ART UNIT	PAPER NUMBER
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3767

DATE MAILED: 11/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/530,817

Applicant(s)

ALHEIDT ET AL.

Examiner

Laura C. Schell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 4/8/05 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Drawings

The drawings are objected to because Fig. 1 uses reference number "69" to label the stopper, when it is used as a label for the septum in Fig. 5.

The drawings are objected to because Figs. 3 and 4 both use "39" to point to different ends of the needle hub.

The drawings are objected to because reference number "37" in Fig. 5 points to different ends of the needle hub.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: reference number "63" in Figs. 2 and 5 are not found within the specification.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an

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application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

Claim 1, is objected to because of the following informalities: line 6 has both a comma and a period next to each other, the period should be deleted.

Claim 17 is objected to because in line 18, the words "contactsand" are not separated by a space.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1-6, 10 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Palmer (US Patent No. 4,820,272). Palmer discloses a syringe (Fig. 1) which is perfectly capable of being used as an IV flush syringe, comprising: a barrel (11) having an inside surface defining a chamber (below 24) for retaining fluid, an open proximal end (10) and a distal end (near 15) including a distal wall with an elongate tip extending

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distally therefrom (15) having a passageway therethrough (passage is through 15) in fluid communication with the chamber; a plunger (12) including an elongate body (22) having a proximal end (near 23) and a distal end (near 26) and a flexible stopper (24; col. 2, lines 42-43) slidably positioned in fluid-tight engagement with said inside surface of said barrel for drawing fluid into and driving fluid out of said chamber by movement of said stopper relative to said barrel, said elongate body portion extending outwardly from said open proximal end of said barrel (Fig. 1); and an anti-reflux means (18) for holding said stopper in a partially deflected position when fluid has been delivered from said chamber and said stopper is in contact with said distal wall (col. 2, lines 46-55; col. 3, lines 29-33).

In reference to claim 2, Palmer discloses that the anti-reflux means includes said stopper having an outwardly projecting rib (25), and said inside surface of said barrel including a recess (21) for receiving said rib when said stopper is in contact with said distal wall.

In reference to claim 3, Palmer discloses that the rib is an annular rib (25) and said recess is an annular recess (21).

In reference to claim 4, Palmer discloses that the anti-reflux means includes a contact area (18) on said inside surface of said barrel at the distal end of said barrel, said contact area having a higher coefficient of friction than said inside surface outside of said contact area (clearly the detention rings (21) in area (18) create a higher coefficient of friction which inherently helps prevent further movement of the plunger) for engaging said stopper when said stopper is in contact with said distal wall of said barrel.

In reference to claim 5, Palmer discloses that the contact area includes a plurality of annular deformations (Fig. 2, 21).

In reference to claim 6, Palmer discloses that the annular deformations are annular projections on said inside surface of said barrel (Fig. 2, 21).

In reference to claim 10, Palmer discloses a needle assembly (16) including a cannula (16) having a proximal end (near 15), a distal end (end furthest from 15) and a lumen therethrough, and a hub (near 15) having an open proximal end containing a cavity and a distal end attached to said proximal end of said cannula so that said lumen is in fluid communication with said cavity, said needle assembly being removably attached (col. 2, lines 22-24) to said tip of said barrel through engagement of said tip to said cavity so that said lumen is in fluid communication with said chamber.

In reference to claim 11, Palmer discloses that the stopper is made from rubber (col. 2, lines 42-43).

Claim 12 is rejected under 35 U.S.C. 102(b) as being anticipated by Lynn (US Patent No. 5,522,804). Lynn discloses an IV flush syringe (Fig. 13) comprising: a barrel (210) having an inside surface defining a chamber (see Fig. 1 for better labeling of the syringe, Fig. 1 near 14 for the chamber) for retaining fluid, an open proximal end (near 110) and a distal end (near 18) including a distal wall with an elongate tip (18) extending distally therefrom having a passageway therethrough in fluid communication with said chamber; a plunger (Fig. 13, 234) including an elongate body portion having a proximal end (end opposite 274), a distal end (near 250) and a flexible stopper (274) slidably positioned in fluid-tight engagement with said inner surface of said barrel for drawing

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fluid into and drawing fluid out of said chamber by movement of said stopper relative to said barrel, said elongate body portion extending outwardly from said open proximal end of said barrel (see Fig. 3a for example); a tip cap (Fig. 7c, 124) releasably connected to said tip of said syringe barrel for sealing said passageway; a quantity of flush solution in said chamber between said stopper and said distal wall (Fig. 7c discloses that the syringe obtains the flush solution, saline (130) from the pouch by drawing it into the chamber area (seen in Fig. 7c as area 26), and better described by col. 14, lines 20-30); and anti-reflux means (Fig. 13, 220) for holding said stopper in a partially deflected position with fluid has been delivered from said chamber and said stopper is in contact with said distal wall (col. 19, lines 9-10).

In reference to claim 13, Lynn discloses that the anti-reflux means includes said stopper having an outwardly projecting rib (Fig. 13 discloses that 274 has an outwardly projecting rib) and said inside surface of said barrel including a recess for receiving said rib when said stopper is in contact with said distal wall (Fig. 13 has an annular detent 220 on the inside wall to receive the rib; col. 19, lines 9-10).

In reference to claim 14, Lynn discloses that the anti-reflux includes a contact area on said inside surface (220) of said barrel at the distal end of said barrel, said contact area having a higher coefficient of friction than said inside surface outside of said contact area for engaging said stopper when said stopper is in contact with said distal wall of said barrel (clearly the detent 220 is an area of a higher coefficient of friction which is what causes the projection 274 to catch within the area and prevent further movement of the plunger).

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In reference to claim 15, Lynn discloses that the flush solution is saline flush solution (130).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palmer (US 4,820,272) in view of Lynn (US Patent No. 5,522,804). Palmer discloses the device substantially as claimed except for a tip cap and flush solution. Lynn, however, discloses a flushing syringe (Figs. 13 and 7c) with a tip cap (Fig. 7c, 124) and flushing solution in the chamber of the syringe, wherein the flushing solution is saline (Fig. 7c, 130; Fig. 7c discloses that the syringe obtains the flush solution, saline (130) from the pouch by drawing it into the chamber area (seen in Fig. 7c as area 26), and

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better described by col. 14, lines 20-30). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Palmer with a cap and the use of saline solution, as taught by Lynn, in order to seal the end of the syringe and to provide the syringe with a flushing solution, since the syringe of Palmer is structurally equivalent to a flushing syringe and is therefore perfectly capable of being used as a flushing syringe.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lynn (US Patent No. 5,522,804), herein after referred to as "Lynn '804", in view of Lynn et al. (US Patent No. 5,743,886), herein after referred to as "Lynn '886". Lynn '804 discloses an IV flush syringe (Fig. 13) comprising: a barrel (210) having an inside surface defining a chamber (see Fig. 1 for better labeling of the syringe, Fig. 1 near 14 for the chamber) for retaining fluid, an open proximal end (near 110) and a distal end (near 18) including a distal wall with an elongate tip (18) extending distally therefrom having a passageway therethrough in fluid communication with said chamber; a plunger (Fig. 13, 234) including an elongate body portion having a proximal end (end opposite 274), a distal end (near 250) and a flexible stopper (274) slidably positioned in fluid-tight engagement with said inner surface of said barrel for drawing fluid into and drawing fluid out of said chamber by movement of said stopper relative to said barrel, said elongate body portion extending outwardly from said open proximal end of said barrel (see Fig. 3a for example); a quantity of flush solution in said chamber between said stopper and said distal wall (Fig. 7c discloses that the syringe obtains the flush solution, saline (130) from the pouch by drawing it into the chamber area (seen in Fig. 7c as area 26), and better

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described by col. 14, lines 20-30); and anti-reflux means (Fig. 13, 220) for holding said stopper in a partially deflected position with fluid has been delivered from said chamber and said stopper is in contact with said distal wall; and providing a catheter having a proximal end, a distal end and a passageway therethrough and a housing having a hollow interior connected to said catheter and in fluid communication with said passageway (Fig. 15g). Lynn '804, however, does not disclose the steps of flushing a catheter nor an access valve on the catheter.

Lynn '886, however, discloses an IV flushing syringe (col. 14, lines 58-64), along with an access valve (col. 15, line 16) on the catheter. Lynn further discloses the steps of flushing the catheter, including: placing said distal end of said catheter in a blood vessel; engaging said elongate tip of said barrel with said access valve so that said passageway of said syringe barrel is in fluid communication with said hollow interior of said housing (col. 15, lines 15-17); applying force to said plunger to move said stopper in a distal direction with respect to said barrel so that said flush solution in said chamber flows through said passageway into said hollow chamber of said housing through said passageway of said catheter (col. 15, lines 17-29); continue applying force to the plunger until said stopper contacts and presses against said distal wall of said barrel (col. 15, lines 29-33). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Lynn '804 with the specified method steps of flushing a catheter, as taught by Lynn '886, as both Lynn '804 and Lynn '866 teach flushing syringes, and both teach attaching the syringes to catheters (again, see Lynn '804 Fig. 15g).

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lynn (US Patent No. 5,522,804), herein after referred to as "Lynn '804", in view of Lynn et al. (US Patent No. 5,743,886), herein after referred to as "Lynn '886". Lynn '804 discloses the method substantially as claimed, including providing a syringe assembly including: a barrel (210) having an inside surface defining a chamber (see Fig. 1 for better labeling of the syringe, Fig. 1 near 14 for the chamber) for retaining fluid, an open proximal end (near 110) and a distal end (near 18) including a distal wall with an elongate tip (18) extending distally therefrom having a passageway therethrough in fluid communication with said chamber; a plunger (Fig. 13, 234) including an elongate body portion having a proximal end (end opposite 274), a distal end (near 250) and a flexible stopper (274) slidably positioned in fluid-tight engagement with said inner surface of said barrel for drawing fluid into and drawing fluid out of said chamber by movement of said stopper relative to said barrel, said elongate body portion extending outwardly from said open proximal end of said barrel (see Fig. 3a for example); a quantity of flush solution in said chamber between said stopper and said distal wall (Fig. 7c discloses that the syringe obtains the flush solution, saline (130) from the pouch by drawing it into the chamber area (seen in Fig. 7c as area 26), and better described by col. 14, lines 20-30); and anti-reflux means (Fig. 13, 220) for holding said stopper in a partially deflected position with fluid has been delivered from said chamber and said stopper is in contact with said distal wall; and providing a catheter having a proximal end, a distal end and a passageway therethrough and a housing having a hollow interior connected to said catheter and in fluid communication with said passageway (Fig. 15g). Lynn '804,

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however, does not disclose the steps of flushing a catheter nor a needle assembly on the syringe or an access valve on the catheter.

Lynn '866, however, discloses a flushing syringe (col. 14, lines 58-59) with a needle assembly (Fig. 10, 90') including a cannula having a proximal end (end that is closest to the plunger), a distal end (end in the saline) and a lumen therethrough and a hub having an open proximal end containing a cavity (end that connects to 14) and a distal end attached to said proximal end of said cannula so that said lumen is in fluid communication with said cavity, said needle assembly being attached to said tip of said barrel (at 14) so that said lumen is in fluid communication with said chamber. Lynn '866 further discloses an access valve on the catheter (col. 15, line 16). Lynn further discloses the method steps of: placing said distal end of said catheter in a blood vessel; engaging said elongate tip of said barrel with said access valve so that said passageway of said syringe barrel is in fluid communication with said hollow interior of said housing (col. 15, lines 15-17); applying force to said plunger to move said stopper in a distal direction with respect to said barrel so that said flush solution in said chamber flows through said passageway into said hollow chamber of said housing through said passageway of said catheter (col. 15, lines 17-29); continue applying force to the plunger until said stopper contacts and presses against said distal wall of said barrel (col. 15, lines 29-33). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Lynn '804 with the specified method steps of flushing a catheter, as taught by Lynn '886, as both Lynn '804 and Lynn '866

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teach flushing syringes, and both teach attaching the syringes to catheters (again, see Lynn '804 Fig. 15g).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Schell whose telephone number is (571) 272-7881. The examiner can normally be reached on Monday-Friday 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LCS

LCS

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

